

Application No.: 09/989965

Case No.: 56732US002

Remarks

The specification has been amended to edit the definition of the "exhalation valve." This amendment raises no new issues. The specification provides plenty of support for a valve that is adapted for use on a filtering face mask. Accordingly, no new issues are presented by this change, and it should be entered into the record.

Claims 57 and 58 have been amended to overcome the rejection under 35 USC § 112, second paragraph. No new issues are raised by deleting the word "preferably" from these claims. Indeed, one is eliminated. Accordingly, this amendment should be entered as well. Applicants thank the Examiner for noting this error.

Claims 1 and 45 have been rejected as being indefinite for using of the term "the other layer." The Examiner indicates that there is insufficient antecedent basis for this limitation. Applicants respectfully submit that this rejection cannot be sustained because the antecedent basis for "the other layer" may be found earlier in the claim where it recites the "first and second layers." At least one of these layers is stiffer than the other. When this language is interpreted according to its ordinary or plain meaning, applicants can see no other interpretation that a person of ordinary skill could arrive at. As such, the claim cannot be properly considered to be vague or indefinite under the terms of 35 USC § 112, second paragraph.

Claims 71-78 also have been rejected under 35 USC § 112, second paragraph, because the term "the pressure drop" has no antecedent basis. Applicants respectfully submit that this rejection also cannot be sustained because the term "the pressure drop" is an *inferentially* recited performance feature of the filtering face mask. Therefore the claim is properly worded as written.

Claims 85-92 have been rejected under 35 USC § 102(b) for being anticipated by U.S. Patent 5,355,910 to Gies et al. (Gies). This rejection cannot be sustained because Gies does not disclose an exhalation valve. The Examiner maintains the rejection, however, because he ignores the preamble claim limitation "an exhalation valve." In so doing, the Examiner cites *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) as support for his position that no weight should be given to the preamble language.

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Applicants' attorney has carefully reviewed the cases cited by the Examiner and has not found any precedential support for the Examiner's position. The former case, *In re Hirao*, only comments on the meaning of the preamble that is used by Hirao et al. in their claim 1. That is, the CCPA only stated what the preamble recited: it did not hold that the preamble language could be ignored. In construing the preamble language, the CCPA found that the preamble limitation was a pertinent part of the claim and that the language furnished the claim with breadth narrower than the Patent Office was attempting to give it:

The Solicitor points to the preamble of claim 1, which recites a "process for preparing foods and drinks sweetened mildly," as showing that the subject matter as a whole involves the use of an old sweetening agent in a very obvious manner. However, the preamble merely recites the purpose of the process; the remainder of the claim (the three process steps) does not depend on the preamble for completeness, and the process steps are able to stand alone. See *Kropa v. Robie*, 38 CCPA 858, 187 F.2d 150, 88 USPO 478 (1951). The Solicitor's interpretation of the preamble would improperly broaden the scope of the claim. (emphasis theirs)

Thus, *In re Hirao* certainly does not indicate that the preamble limitation can be ignored. Too the contrary, *In re Hirao* cautions the PTO against not giving the limitation the proper weight, construction, or meaning, which it deserves.

The second case cited by the Examiner also does not support the position taken in the Office Action. In *Kropa v. Robie*, the CCPA found that the preamble term "an abrasive article" was a "vital term" to the claim, which term gave the claim life and meaning and therefore could not be ignored:

In the case before us, the words "An abrasive article" are essential to point out the invention defined by the counts. In our judgment those introductory words give life and meaning to the counts, for it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable inter alia of use as abrasive grains and a binder is not an "abrasive article." The term calls forth a distinct relationship between the proportions of grain and resin comprising the article. It is important here, as it was in *Hall v. Shimadzu*, 19 C.C.P.A. (Patents) 1288, 59 F.2d 225, 13 USPO 259, that the interference counts originated in one party's patent where the entire object of the patent is expressed in the introductory clause of the counts--an objective which nowhere appears in the other party's disclosure (here, appellant's 1938 applications). The term "abrasive article" is a vital term of the counts, and the

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meaning must be taken from the application in which the counts originated.  
Kenyon v. Crane, 28 C.C.P.A. (Patents) 1208, 120 F.2d 380, 49 USPQ 707. We hold that it is a limitation which is material to the issue, and must be observed.

Similarly, in the present case, the phrase "an exhalation valve" gives life and meaning to applicants' claim. Not every valve seat and flexible flap is capable of being used as an exhalation valve. The term provides a distinct relationship between these elements such that they would be valuable for use in purging air from the interior of a filtering face mask. In fact, this preamble term, being so distinctly defined in the specification, would never allow the claim to read on a relief valve for a motor vehicle. The Examiner is reminded that every limitation in a claim is important and must be considered in construing the claim.<sup>1</sup> It is legal error to ignore claim limitations.<sup>2</sup> The Examiner is aware that the inquiry during examination is patentability of the invention as the applicant regards it.<sup>3</sup> The record unequivocally shows that applicants do not regard "an exhalation valve" to include a relief valve for a motor vehicle. In addition to the cases cited by the Examiner, there are other decisions that provide precedent for giving the preamble limitation proper weight or consideration.<sup>4</sup> Thus under a proper construction of the law, claims 85-92 cannot be properly viewed as being anticipated by Gies.

Claims 1-9, 13-35, 40-52, 56-78, and 83-84 have been rejected under 35 USC § 103 as being unpatentable over U.S. Patent 5,325,892 to Japuntich et al. (Japuntich) in view of Gies. Applicants respectfully submit that this rejection cannot be sustained for the reasons presented in the Amendment mailed on September 30, 2003. One of the reasons asserted by applicants for non-obviousness was that the record does not contain any evidence for making the Japuntich/Gies combination. In response, the Examiner stated that Japuntich and Gies can be combined because of "knowledge generally available to one of ordinary skill in the art." The problem with this position, however, is that the Examiner does not identify any such knowledge. The record presently is entirely devoid of any evidence of the so-asserted, generally available

<sup>1</sup> *Glaxo Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1566, 42 USPQ2d 1257, 1261 (Fed. Cir. 1997) ("It is elementary patent law that all limitations are material.").

<sup>2</sup> *Id.*

<sup>3</sup> *In re Zletz*, 13 USPQ2d 1320, 1322 ("Thus the inquiry during examination is patentability of the invention as 'the applicants regards' it; and if the claims do not 'particularly point out and distinctly claim', in the words of Section 112, that which examination shows the applicant is entitled to claim as his invention, the appropriate PTO action is to reject the claims for that reason.").

<sup>4</sup> See e.g., *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) (The term "angioplasty" in a preamble reciting a "balloon angioplasty catheter" was considered to be a structural limitation).

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knowledge. Applicants therefore request that the Examiner make the record clear as to what "knowledge" is being using to sustain the rejection. In the absence of such evidence, the rejection must be withdrawn.<sup>5</sup>

The law is very clear on this point. If there is some general knowledge that exists in the art as to why a person of ordinary skill would have combined the teachings of a relief valve for a passenger compartment with a filtering face mask, the Examiner should, at a minimum, at least explain what that knowledge is.<sup>6</sup> It is entirely improper for the Examiner to state that two distinctly different references may be combined based on a "knowledge generally available to one of ordinary skill" but then never put that knowledge into the record.<sup>7</sup>

On page 20 of the last Office Action, the Examiner asked applicants to produce "binding legal precedent that stipulates that the common law four corners doctrine of contract law applies to patent prosecution and trumps the ordinary observer standard in evaluation evidence." Applicants do not understand the Examiner's reference to contract law here. Applicants believe that the Examiner is referring to applicants' comment in the first sentence on page 17 of the Amendment mailed September 30, 2003. In that portion of applicants' response, applicants stated that the total record (i.e., the "four corners of the record") did not contain any evidence of a teaching or suggestion to combine Japuntich with Gies. In the earlier Office Action, the Examiner held that Japuntich and Gies would be combinable because "[t]he suggestion/motivation for doing so would have been to provide for a more effective valve operation to achieve the objects of the invention contemplated by Japuntich (see Summary of the invention) which Gies stipulates such types of operable features are in accord with and more effectively/reliably obtainable via his reed valve structure (summary of invention, note recitations of enhanced seal characteristics, control of flow and operation of the valve)." The problem with this earlier position is that Gies does not address any of the objects contemplated by Japuntich. Thus, the record, as it presently stands, fails to contain any evidence of a teaching, suggestion, or motivation to combine Japuntich and Gies.

<sup>5</sup> *In re Lee*, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002) ("Thus when they rely on what they assert to be general knowledge to negate patentability, that knowledge must be articulated and placed on the record. The failure to do so is not consistent with either effective administrative procedure or effective judicial review.").

<sup>6</sup> *Winner Int'l Royalty Corp. v. Wang*, 53 USPQ2d 1580, 1586-87 (Fed. Cir. 2000) ("[T]he showing of combinability, in whatever form, must nevertheless be 'clear and particular.'").

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The Japuntich valve was designed to maintain a seal under any orientation of the valve, while providing minimal pressure drop during an exhalation. Gies certainly is not concerned with producing a valve that remains closed under any orientation. Gies uses his valve on a motor vehicle for pressure relief purposes. Passenger compartment valves have no need to remain closed under any orientation. In addition, Gies does not address any need for a valve that can open under minimal exhalation pressure. The force exerted by slamming a motor vehicle door is certainly magnitudes larger than the force exerted by a person's exhalation breath. Thus, the suggestion or motivation for combining Japuntich with Gies does not exist in the present record. This was the thrust of applicants' position in the first sentence on page 17 of applicants' prior Amendment.

In view of the above, the only remaining basis for combining Japuntich with Gies appears to be some vaguely recited knowledge that persons of ordinary skill possess. As indicated above, the record, however, must be made clear as to what this knowledge is, or the rejection must be withdrawn. As the Federal Circuit said in *W.L. Gore*, "[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher."<sup>8</sup> A vague reference to common knowledge and common sense is not a substitute for evidence.<sup>9</sup> If the Examiner is still relying on his earlier position that Gies addresses the objects of Japuntich (despite no apparent need for these objects in a motor vehicle pressure relief valve or vice versa) this too should be made clear. In short, the record must contain some *evidence* of a suggestion to combine the teachings of these two manifestly different references.<sup>10</sup> Mere

<sup>7</sup> See, *Lee*, 61 USPQ2d at 1435; see also *In re Peehs*, 204 USPQ 835, 837 (CCPA 1980) ("[I]t is incumbent upon the PTO to explain its reasons if it disagrees. A mere conclusory statement...is inadequate.").

<sup>8</sup> *W.L. Gore v. Garlock Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (emphasis added).

<sup>9</sup> *In re Lee*, 61 USPQ2d 1430, 1435 (Fed. Cir. 2002) ("Common knowledge and common sense, even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.").

<sup>10</sup> *In re Fritch*, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. Wilson and Hendrix fail to suggest any motivation for, or desirability of, the changes espoused by the Examiner and endorsed by the Board.").

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opinions or bald conclusions do not suffice.<sup>11</sup> An invention is not obvious without a suggestion to make the modification.<sup>12</sup>

As the Examiner is aware, it is not proper to view the applicants' invention in retrospect, once having learned of their discovery. Applicants' specification is the only document that teaches using a multi-layered flap in an exhalation valve. Applicants' specification also is the only document that explains the benefits of using such a valve on a filtering face mask. These facts provide very good evidence of nonobviousness.<sup>13</sup> The prior art does not teach or suggest what applicants have done; nor does it appreciate the benefits that the multi-layered flap provides.

The inventors discovered that the use of a multi-layered flexible flap in a unidirectional fluid valve can provide performance benefits to an exhalation valve for a filtering face mask. In particular, the inventors discovered that a thinner and more dynamic flexible flap may be used in some instances, which can allow the valve to open easier under less pressure drop to enable warm, moist, exhaled air to escape from the mask interior under less exhalation pressure. Wearers therefore may be able to purge larger amounts of exhaled air from the interior gas space more rapidly without expending as much power, resulting in improved comfort to the mask wearer.

The inventors also discovered that a larger process window may be available to manufacturers of the flaps for exhalation valves. When making flapper-style exhalation valves, the thickness and stiffness of the flap material generally needs to be carefully controlled so that the appropriate beam stiffness can be achieved for the flap — otherwise, the valve may be subject to leakage at the point where the flap contacts the valve's seal surface. When making a multi-layered flap of the present invention, however, flap-to-flap variability may not need to be so tightly controlled during the manufacturing process because one layer in the flap can be easily fashioned to

<sup>11</sup> See, *Lee*, 61 USPQ2d at 434 ("The examiner's conclusory statements that 'the demonstration mode is just a programmable feature which can be used in many different devices[s] for providing automatic introduction by adding the proper programming software' and that 'another motivation would be that the automatic demonstration mode is user friendly and it functions as a tutorial' do not adequately address the issue of motivation to combine. This factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").

<sup>12</sup> *In re Lakowski*, 10 USPQ2d 1397, 1399 (Fed. Cir. 1989).

<sup>13</sup> *In re Saether*, 181 USPQ 36, 40 (CCPA 1974) ("In addition to the differences from the prior art, which is shown by the references and by appellant's specification, further evidence of unobviousness is shown by the improvements and unexpected results obtained by the claimed invention.").

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provide the flap with its desired beam stiffness. Overall flap thickness tolerances then do not need to be so tightly controlled during manufacture. The structure and benefits of the new exhalation valve may also be applied to an inhalation valve, where the flow through the valve is likewise unidirectional and where improvements in pressure drop across the valve are similarly beneficial to wearer comfort.

In view of these benefits and the differences in structure that provide the benefits, applicants have surely made a patentable contribution to the art.

In regard to the issue of whether Gies is an analogous reference, applicants are having trouble understanding the Examiner's position. Does the Examiner believe that Gies is analogous only because the reference is in applicants' field of endeavor or does the Examiner also believe that Gies is reasonably pertinent to the problem with which the applicant was concerned? Presently, the Examiner only appears to suggest that Gies resides in the respiratory arts and therefore is in applicants' field of endeavor. If this is the only basis that the Examiner is using for holding that Gies is an analogous reference, please so state in the next official communication so that the record is clear. Because if the Examiner is only relying on the first part of the test to find that Gies is analogous, applicants respectfully assert that the Examiner is painting with a very broad brush in defining the field of endeavors for which the applicants' invention and the Gies patent reside.

Applicants' invention pertains to a filtering face mask that uses an exhalation valve. An exhalation valve operates under the cadence of a persons' breathing rate, and the valve desirably remains seated or closed under any orientation of the mask and yet is able to open under minimal exhalation pressure when a wearer exhales. The goal of applicants' invention is to purge larger amounts of exhaled air from the mask interior, more rapidly, without expending as much power, which results in improved comfort to the mask wearer. The field of filtering face masks for exhalation valves is a far cry from the field of automobile passenger compartment relief valves, which operate when a person slams the vehicle door shut.

The Examiner attempts to assert a common field by broadly casting both applicants' field and Gies' field as being in the "respiratory arts". The field "respiratory arts" could include many things unrelated to filtering face masks, such as medical devices or drug delivery systems that are used to improve breathing in, for example, patients with asthma or emphysema. But even if the

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test for determining whether a reference was analogous merely depended on whether the English language could be used to craft some overlapping commonality amongst different arts, the attempt to do here would nonetheless fail because a pressure relief valve for a motor vehicle has nothing to do with respiration.

In the next Office Action, it would be helpful if the Examiner could elaborate on how Gies allegedly resides in the respiratory arts, if this rejection is intended to be maintained on this basis. It would also be helpful if the Examiner could explain why the broadly cast field of "respiratory arts" is being used, as opposed to the field of "filtering face masks". If the Examiner also takes the position that Gies is analogous because it provides a disclosure that is "reasonably pertinent to the problem of which the applicant was concerned", applicants respectfully ask that the Examiner make the record clear as to what "particular problem with which the applicant was concerned" is addressed by Gies. Although the Examiner also bolded the second portion of the two-part test for determining whether a reference is analogous, no cogent reasoning or explanation has yet been provided to set forth the "particular problem with which the applicant was concerned."

Finally, the Examiner indicates that the open-ended claim language, as used in applicants' claims, precludes the Examiner from giving any weight to the arguments regarding the effect of gravity on applicants' valve. The Examiner is reminded, however, that the claims are used only to define the metes and bounds of the subject matter being claimed. The remarks section in an Amendment or Response is what is used to present arguments. The arguments do not also need to be set forth in the claim in order for them to be considered. The Examiner is also reminded that there is no need to recite the advantages in a claim for them to be considered.<sup>14</sup> The advantages and properties of an invention must be considered, regardless of being recited in the claim. The "invention as a whole" requirement set forth in 35 USC § 103 demands that all aspects of an invention be considered in evaluating obviousness under 35 USC § 103.<sup>15</sup>

<sup>14</sup> *In re Estes*, 164 USPQ 519, 521 (CCPA 1970) ("There can be no doubt from the record that these advantages accrue from the claimed process, it is not required that they be recited [in the claims].").

<sup>15</sup> *In re Papesch*, 137 USPQ 43 (CCPA 1963); *In re von Schickh*, 150 USPQ 300, 302 (CCPA 1966).



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Please reconsider the Section 112 and the prior art rejections in light of the above remarks.

Respectfully submitted,

Date

1-16-04

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<b>Substitute for form 1449A/PTO (modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets if necessary)  Page 1 of 1	<b>Application Number</b>	09/889965
	<b>Filing Date</b>	November 21, 2001
	<b>First Named Inventor</b>	Martin, Philip G.
	<b>Art Unit</b>	
	<b>Examiner Name</b>	
	<b>Attorney Case Number</b>	56732US002

U.S. Patent Documents					
Exam. Init.*	Cite No.	Document Number	Publication Date or Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Doc. Number (Kind Code If Known)			
	A1	US- 6,047,698	04-11-00	Magidson et al.	
	A2	US- 5,687,767	11-18-97	Bowers	
	A3	US- 5,509,436	04-23-96	Japuntich et al.	
	A4	US- 5,325,892	07-05-94	Japuntich et al.	
	A5	US- 4,934,362	06-19-90	Braun	
	A6	US- 4,630,604	12-23-86	Montesi	
	A7	US- 4,306,584	12-22-81	Schlobohm	
	A8	US- 3,557,265	01-91-71	Chisholm et al.	
	A9	US- 2,895,472	07-21-59	Matheson	
	A10	US- 2,230,770	02-04-41	Van Almelo	
	A11	US- 2,072,516	03-02-37	Ferenci et al.	

Foreign Patent Documents							
Exam. Init.*	Cite No.	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Translation (Check if yes)
		Ctry. Code	Number-KindCode (if known)				
	B1	EP	0928917 A1	07-14-99			
	B2	FR	2688287	09-10-93			X
	B3						
	B4						
	B5						
	B6						
	B7						

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	
	C2	
	C3	

\*Examiner:

Date Considered:

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<b>Substitute for form 1449A/PTO (modified)</b>  <b>INFORMATION DISCLOSURE</b>  <b>STATEMENT BY APPLICANT</b>	<b>Application Number</b>	<b>09/989965</b>
	<b>Filing Date</b>	<b>November 21, 2001</b>
	<b>First Named Inventor</b>	<b>Martin, Phillip G.</b>
	<b>Art Unit</b>	
	<b>Examiner Name</b>	
	<b>Attorney Case Number</b>	<b>56732US002</b>

**RELATED U.S. APPLICATIONS - DO NOT PRINT**[illegible]

\*Examiner:

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Information Disclosure Statement — PTO-1449 (Modified)

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	<b>Filing Date</b>	November 21, 2001
	<b>First Named Inventor</b>	Martin, Philip G.
	<b>Art Unit</b>	3753
	<b>Examiner Name</b>	
	<b>Attorney Case Number</b>	56732US002

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	A1	US-			
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	A10	US-			
	A11	US-			

Foreign Patent Documents							
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		Ctry. Code	Number-KindCode (if known)				
	B1	FR	2,641,597	7/13/90			
	B2	GB	504,232 A	4/21/39			
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
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	C2	
	C3	

<b>*Examiner:</b>	<b>Date Considered:</b>
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